APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,561	09/25/2001	J. Gregor Sutcliffe	TSRI 401.0D5	3947

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EXAMINER
KENEDY, ANDREW A

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	09/965,561	SUTCLIFFE ET AL.
	Examiner	**Art Unit**	
	Andrew A. Kenedy	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
    closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>38-43</u> is/are pending in the application.

    4a) Of the above claim(s) <u>41-43</u> is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>38-40</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) <u>38-43</u> are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on <u>25 September 2001</u> is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

       1.☐ Certified copies of the priority documents have been received.

       2.☐ Certified copies of the priority documents have been received in Application No. _____.

       3.☐ Copies of the certified copies of the priority documents have been received in this National Stage
         application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
    Paper No(s)/Mail Date <u>09964597,08152482</u>.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (claims 38-40) in the response dated July

28, 2003, is acknowledged. Claims 41-43 are withdrawn from further consideration pursuant to

37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or

linking claim.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37

CFR 1.67(a) identifying this application by application number and filing date is required. See

MPEP §§ 602.01 and 602.02. The oath or declaration is defective because:

This application presents a claim for subject matter not originally claimed or embraced in

the statement of the invention of the parent applications from which the instant application

derives, as follows: The instant application is claimed as a division of parent application

09/316349 (issued patent No. 6309834), which is claimed as a division of parent application

09/035190 (issued patent No. 6030784). Parent application 09/316349 does not disclose

transformation of a database entry, determining index sequences, or graphically displaying the

length of a correlate sequence in relation to an index sequence. Furthermore, the terms "index

sequence(s)" and "correlate sequence(s)" do not appear within that application. Parent

application 09/035190 does not disclose transformation of a database entry, choosing a source

sequence from a database for transformation, determining index sequences, determining correlate

sequences, or graphically displaying the length of a correlate sequence in relation to an index

sequence. Furthermore, the terms "index sequence(s)" and "correlate sequence(s)" do not appear

anywhere within that application. Therefore, applicants' instant application may qualify as a

continuation-in-part, but not as a divisional as claimed.

A supplemental oath or declaration is required under 37 CFR 1.67. The new oath or

declaration must properly identify the application of which it is to form a part, preferably by

application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01

and 602.02.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 38-40 are rejected under the judicially created doctrine of obviousness-type

double patenting as being unpatentable over Claims 1, 11 and 12 of U.S. Patent No.

6309834 in view of Guilfoyle et al. (US 6280948 B1).

With respect to Claim 38, U.S. Patent No. 6309834 claims a method of recognizing

sequence identities and similarities between the sequence of 3'-ends of mRNA molecules present

in a sample and a database of sequences. Claim 1(m) requires determining corresponding

nucleotide sequences (determining a correlate sequence within a source sequence) from a

database of nucleotide sequences (choosing a source sequence from a polynucleotide database

entry), said corresponding nucleotide sequences being delimited by a endonuclease recognition

site and the poly(A) tail (locating a poly(A) tail sequence, locating an endonuclease recognition

site, and determining a correlate sequence within the source sequence including the sequence

bounded by the poly(A) tail and the endonuclease recognition site and including at least part of

the endonuclease site); and comparing the sequence of the cloned cDNA to the corresponding

nucleotide sequences, thereby recognizing sequence identities and similarities between the

sequence of 3'-ends of mRNA molecules present in a sample and a database of sequences

(determining the length of the correlate sequence, the location and sequence of the poly(A) tail,

the location and sequence of the endonuclease recognition site, and the length of the correlate

sequence in relation to the source sequence).

While U.S. Patent No. 6309834 does not teach storing the above information, it would

have been obvious to one of ordinary skill in the art to store the above results in a database to

produce a transformed sequence database entry since the above methods are performed by

retrieving and manipulating sequence information stored in computerized databases.

U.S. Patent No. 6309834 also does not teach the limitation of determining an index

sequence consisting of about 2 to about 6 nucleotides adjacent to the endonuclease recognition

site.

Guilfoyle et al. teaches a method of indexing sequences – including polynucleotides

representing the 3'-end of an mRNA having a poly(A) tail sequence -- by using short index

sequences, preferably 3 to 5 nucleotides long, adjacent to endonuclease recognition sites of the

polynucleotide sequences (see at least the abstract; Fig. 1-5; col. 5, lines 39-63; col. 12, lines 60-

64; and Claims 1-3).

It would have been obvious for one of ordinary skill in the art to combine the teachings of

Guilfoyle et al. with U.S. Patent No. 6309834, since Guilfoyle et al. teaches that determination

and utilization of an indexing sequence adjacent to an endonuclease recognition site at the end of

a nucleotide sequence representing the 3'-end of an mRNA allows for generating "fingerprints"

that can be "useful for creating and searching EST databases" and in RNA profiling (see at least

col. 15, line 20 – col. 16, line 19; and col. 12, lines 60-64).

With respect to Claim 39, U.S. Patent No. 6309834 teaches comparing and displaying the

lengths of the above corresponding nucleotide sequences in a two dimensional graphical display,

thereby making it obvious to also display the length of the corresponding nucleotide sequence

(the correlate sequence) in relation to the index sequence (see at least Claim 4(q)).

With respect to Claim 40, U.S. Patent No. 6309834 teaches that the restriction

endonuclease can be Msp1, Taq1, or HinP1I (see at least Claims 11 and 12).

Claims 38-40 are rejected under the judicially created doctrine of obviousness-type

double patenting as being unpatentable over Claims 1 and 3 of U.S. Patent No. 6633818 in

view of Guilfoyle et al. (US 6280948 B1).

With respect to Claim 38, U.S. Patent No. 6633818 claims a method for simultaneous

comparison of sequences of mRNA's in an mRNA population to data stored on a computer

readable medium. Claim 1(l) requires comparing the data stored on the computer readable

medium to indicate sequence relationship matches of between nucleotide sequences (choosing a

source sequence from a polynucleotide database entry). Claim 1(a)-(b) requires polynucleotide

sequences created using a primer having from 7 to 40 T residues (a poly(A) tail sequence) and a

primer containing neighboring endonuclease recognition site sequence while Claim 1(j) requires

determining the sequence and the length of each polynucleotide sequence representing a 3'-end

of mRNA (locating a poly(A) tail sequence, locating an endonuclease recognition site,

determining a correlate sequence within the source sequence including the sequence bounded by

the poly(A) tail and the endonuclease recognition site and including at least part of the

endonuclease site, and determining the length of the correlate sequence in relation to the source

sequence). Claim 1(k) requires storing the above sequence and length results (storing

information concerning the location and sequence of the poly(A) tail, the location and sequence

of the endonuclease recognition site, and the length of the correlate sequence in relation to the

source sequence, thereby producing a transformed database entry).

U.S. Patent No. 6633818 also does not teach the limitation of determining an index

sequence consisting of about 2 to about 6 nucleotides adjacent to the endonuclease recognition

site.

Guilfoyle et al. teaches a method of indexing sequences – including polynucleotides

representing the 3'-end of an mRNA having a poly(A) tail sequence -- by using short index

sequences, preferably 3 to 5 nucleotides long, adjacent to endonuclease recognition sites of the

polynucleotide sequences (see at least the abstract; Fig. 1-5; col. 5, lines 39-63; col. 12, lines 60-

64; and Claims 1-3).

It would have been obvious for one of ordinary skill in the art to combine the teachings of

Guilfoyle et al. with U.S. Patent No. 6633818, since Guilfoyle et al. teaches that determination

and utilization of an index sequence adjacent to an endonuclease recognition site at the end of a

nucleotide sequence representing the 3'-end of an mRNA allows for generating "fingerprints"

that can be "useful for creating and searching EST databases" and in RNA profiling (see at least

col. 15, line 20 – col. 16, line 19; and col. 12, lines 60-64).

With respect to Claim 39, while U.S. Patent No. 6633818 does not explicitly teach

displaying graphically the length of sequences in relation to each other. However, since the

above method involves storing and comparing the sequence data and results on a computer (see

at least Claim 1), it would have been obvious to one of ordinary skill in the art to display

graphically the length of the correlate sequence in relation to the index sequence on the

computer's graphical display monitor.

With respect to Claim 40, U.S. Patent No. 6633818 teaches that the restriction

endonuclease can be Msp1, Taq1, or HinP1I (see at least col. 7, lines 48-51).

Claim Rejections - 35 USC § 112

Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It appears that the phrase "the first recognition site" refers to the previously mentioned

"poly(A) tail sequence", however, this it is not clear since the poly(A) tail sequence is not

indicated to be a recognition site. Applicant needs to clarify this within the claim.

The phrase "consisting of about two to about six nucleotides" is indefinite as to the

number of nucleotides encompassed since the term "about" does not precisely define the metes

and bounds of the limitation, thereby rendering the scope of the claim uncertain.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 38 and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by

Kinzler et al. (US 6383743 B1).

As discussed previously in regard to the oath/declaration, Claims 38 and 39 of applicants'

instant application are not fully supported by the disclosure of either of parent applications

09/316349 or 09/035190 and therefore do not receive the benefit of priority. Therefore, Kinzler

et al., relied upon in this rejection, is valid prior art under 102(b) against the instant claims.

With respect to Claim 38, Kinzler et al. teaches a method of comparing polynucleotide

sequences with known polynucleotide sequences in a database (choosing a source sequence from

a polynucleotide sequence database entry) (see at least Claim 18); wherein the sequences to be

compared represent the 3-ends of mRNA's and span the length from the poly(A) tail to the

closest endonuclease restriction site (locating a poly(A) tail sequence within the source sequence;

locating the nearest endonuclease recognition site sequence within the source sequence) (see at

least Fig. 1A; col. 5, lines 5-11; and Claim 18); determining a tag sequence as short as 6 to 7

nucleotides (determining an index sequence consisting of about 2 to about 6 nucleotides)

adjacent to the endonuclease recognition site (see at least Fig. 1A-B; col. 2, lines 59-64; and col.

4, lines 52-58); matching a first nucleotide sequence located at a defined position 3' of the 3'-

most endonuclease cleavage site within an mRNA to a second nucleotide sequence in a database

(determining a correlate sequence within the source sequence, the correlate sequence including

the sequence bounded by the poly(A) tail sequence and the endonuclease recognition site) (see at

least Claim 18); determining that the second nucleotide sequence is located at a defined position

within the respective mRNA or cDNA molecule and identifying the first nucleotide sequence

with the sequence in the database (determining the length of the correlate sequence) (see at least

Claim 18); and storing the above information in a computerized data storage system (storing the

information concerning the location and sequence of the poly(A) tail, the location and sequence

of the endonuclease recognition site, and the length of the correlate sequence in relation to the

source sequence, thereby producing a transformed database entry) (see at least col. 10, lines

50-67).

With respect to Claim 39, Kinzler et al. teaches that the sequence information can be

output in graphic form on a computer output device (displaying graphically the length of the

correlate sequence in relation to the index sequence) (see at least col. 10, lines 50-62).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in
> section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are
> such that the subject matter as a whole would have been obvious at the time the invention was made to a person
> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the
> manner in which the invention was made.

Claims 38-40 rejected under 35 U.S.C. 103(a) as being unpatentable over Sutcliffe et

al. (US 6633818 B1) in view of Guilfoyle et al. (US 6280948 B1).

As discussed previously in regard to the oath/declaration, Claims 38-40 of applicants' instant application are not fully supported by the disclosure of either of parent applications 09/316349 or 09/035190 and therefore do not receive the benefit of priority. Therefore, Sutcliffe et al. and Guilfoyle et al., relied upon in this rejection, are valid prior art under 103(a) against the instant claims.

With respect to Claim 38, Sutcliffe et al. (US 6633818 B1) teaches a method for simultaneous comparison of sequences of mRNA's in an mRNA population to data stored on a computer readable medium wherein Claim 1(l) requires comparing the data stored on the computer readable medium to indicate sequence relationship matches of between nucleotide sequences (choosing a source sequence from a polynucleotide database entry). Claim 1(a)-(b) requires polynucleotide sequences created using a primer having from 7 to 40 T residues (a poly(A) tail sequence) and a primer containing neighboring endonuclease recognition site sequence while Claim 1(j) requires determining the sequence and the length of each polynucleotide sequence representing a 3'-end of mRNA (locating a poly(A) tail sequence, locating an endonuclease recognition site, determining a correlate sequence within the source sequence including the sequence bounded by the poly(A) tail and the endonuclease recognition site and including at least part of the endonuclease site, and determining the length of the correlate sequence in relation to the source sequence). Claim 1(k) requires storing the above sequence and length results (storing information concerning the location and sequence of the poly(A) tail, the location and sequence of the endonuclease recognition site, and the length of the

correlate sequence in relation to the source sequence, thereby producing a transformed database

entry).

Sutcliffe et al. also does not teach the limitation of determining an index sequence

consisting of about 2 to about 6 nucleotides adjacent to the endonuclease recognition site.

Guilfoyle et al. teaches a method of indexing sequences – including polynucleotides

representing the 3'-end of an mRNA having a poly(A) tail sequence -- by using short indexing

sequences, preferably 3 to 5 nucleotides long, adjacent to endonuclease recognition sites of the

polynucleotide sequences (see at least the abstract; Fig. 1-5; col. 5, lines 39-63; col. 12, lines 60-

64; and Claims 1-3).

It would have been obvious for one of ordinary skill in the art to combine the teachings of

Guilfoyle et al. with Sutcliffe et al., since Guilfoyle et al. teaches that determination and

utilization of an index sequence adjacent to an endonuclease recognition site at the end of a

nucleotide sequence representing the 3'-end of an mRNA allows for generating "fingerprints"

that can be "useful for creating and searching EST databases" and in RNA profiling (see at least

col. 15, line 20 – col. 16, line 19; and col. 12, lines 60-64).

With respect to Claim 39, while Sutcliffe et al. does not explicitly teach displaying

graphically the length of sequences in relation to each other. However, since the above method

involves storing and comparing the sequence data and results on a computer (see at least Claim

1), it would have been obvious to one of ordinary skill in the art to display graphically the length

of the correlate sequence in relation to the index sequence on the computer's graphical display

monitor.

With respect to Claim 40, Sutcliffe et al. teaches that the restriction endonuclease can be

Msp1, Taq1, or HinP1I (see at least col. 7, lines 48-51).

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kinzler et al.

(US 6383743 B1) in view of Roberts et al. (*Nucleic Acids Research*, 1998).

As discussed previously in regard to the oath/declaration, Claims 40 of applicants' instant

application is not fully supported by the disclosure of either of parent applications 09/316349 or

09/035190 and therefore does not receive the benefit of priority. Therefore, Kinzler et al. and

Roberts et al., relied upon in this rejection, are valid prior art under 103(a) against the instant

claims.

With respect to Claim 40, Kinzler et al. teaches that the endonuclease recognition site can

be a Type II endonuclease site, but does not explicitly mention MspI, TaqI and HinP1I. Roberts

et al. teaches that Type II endonucleases are a class/family of endonucleases that includes MspI,

TaqI and HinP1I (see pg. 344 and 348). It would have been obvious for one of ordinary skill in

the art to combine the teachings of Roberts et al. with the method of Kinzler et al., since Kinzler

et al. does not provide a listing of Type II endonucleases, while Roberts et al. does.

Made of Record

Prior Art made of record which discloses various aspects of applicant's instant invention

but was not relied upon:

<u>Applicants' IDS documents</u>: Adams et al. (exhibit 10) teaches comparing the sequences and

lengths of ESTs (sequences representing the 3'-end of mRNA) using databases; Adams et al.

(exhibit 11) teaches comparing the sequences and lengths of ESTs using databases; Liang et al.

(exhibit 15) teaches the sequencing and comparison of nucleotide sequences containing poly(A)

tail sequence representing the 3'-end of mRNAs.

Contact Information

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Andrew A. Kenedy whose telephone number is (571)-272-0574.

The examiner can normally be reached on Monday-Friday 9:00am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Michael Woodward can be reached on (571)-272-0722. The fax phone number for

the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.A.K. March 15, 2004

MARIANNE P. ALLEN   3/18/04
PRIMARY EXAMINER

AU 1631